REMARKS

Entry of the foregoing and further and favorable reconsideration of the subject application, in view of the following remarks and in accordance with 37 C.F.R. § 1.116, are respectfully requested. By the present amendment, claim 5 has been amended simply to clarify the invention. Support for this amendment to claim 5 may be found, at the very least, on page 2, first paragraph, and the paragraph bridging pages 3 and 4 of the specification as filed. The amendments are consistent with 37 C.F.R. § 1.116, in view of the fact that they place the application in condition for allowance, or at the very least reduce the issues for appeal. Entry is thus believed to be in order. No new matter has been added by the present amendment.

Rejection of Claims 5-9 Under 35 U.S.C. § 112, Second Paragraph

Claims 5-9 have been rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite and incomplete. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

The claims have been amended to recite how the primers are used (in step (a) for amplifying DNA); how the antibodies are used (in step (b) for conducting western blot analysis); and how the DNA encoding for CREM or CREM-dependent proteins are used (in step (c) for conducting northern blot analysis). In light of these amendments to the claims, it is believed that the claims are definite and complete.

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, second paragraph.

Rejection of the Claims Under 35 U.S.C. §§ 102(b) and 103(a)

Claims 5 and 7 have been rejected under 35 U.S.C. § 102(b) for purportedly being anticipated by, or in the alternative under 35 U.S.C. § 103(a) as purportedly being obvious over, Delmas et al (*Mol. Endocrinol. 7*:1502-1514 (1993)). Claim 6 has been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Delmas et al, as applied to claims 5 and 7, and further in view of Bocker et al (*Cell Tissue Res. 278*:595-600 (1994)). Claims 8 and 9 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Delmas et al, as applied to claims 5 and 7, and further in view of Stratagene Catalog, page 39 (1988). For at least all of the reasons set forth below, withdrawal of these rejections is believed to be in order.

The present invention relates to processes for investigating spermatogenesis and monitoring it. These processes involve detecting CREM and/or CREM-dependent proteins by using primers for amplifying DNA coding for CREM and/or CREM-dependent proteins; using antibodies against CREM and/or CREM-dependent proteins in western blot analysis; and/or using DNA encoding for CREM or CREM-dependent proteins in northern blot analysis. The present inventors unexpectedly found that if CREM is not expressed, or is expressed to a reduced extent but not in a phosphorylated form, the CREM-dependent proteins are not expressed, or are expressed to a reduced extent, and there will be an unbalanced spermatogeneis, resulting in non-functioning spermia. The correlation between CREM/CREM-dependent proteins and unbalanced spermatogenesis/non-functioning spermia is shown in applicant's publication Blendy et al, *Nature 380*:162-165 (March 1996), which is attached hereto.

Delmas et al disclose numerous characteristics of CREM. Delmas et al disclose that CREM is expressed only in post-meiotic germ cells and that CREM expression is not related with spermatogenesis, as CREM expression is found in a mutant mouse in which spermatogenesis is arrested during meiosis, and consequently no haploid spermatogenic cells are produced (see Delmas et al, page 1505, right column, paragraph 3).

Delmas et al do not disclose or suggest the correlation between deficient CREM/CREM-dependent proteins and unbalanced spermatogeneis/non-functioning spermia. Since Delmas et al do not recognize or even suggest the possibility of this correlation, Delmas et al could not possibly disclose or suggest detecting and monitoring the presence of CREM and/or CREM-dependent proteins as a means of investigating and monitoring spermatogenesis in a male animal. Therefore, Delmas et al does not disclose or suggest the invention of claims 5 or 7.

Since claim 5 (the broadest claim) is not anticipated by or obvious in view of the primary reference, Delmas et al, its dependent claims (claims 6, 8 and 9) could not possibly be obvious in view of Delmas et al taken together with the secondary references (Bockers et al and the Stratagene Catalog).

In light of these remarks, applicants respectfully request withdrawal of these rejections of the claims under 35 U.S.C. §§ 102(b) and 103(a).

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

In the event that there are any questions relating to this application, the Examiner is invited to telephone the undersigned attorney so that prosecution of the subject application may be expedited.

Respectfully submitted,

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Date: October 24, 2001

Attachment to Amendment and Reply dated October 24, 2001

Marked-up Claim 5

5. (Amended) A process for investigating spermatogenesis and monitoring it, respectively, in a male animal, comprising puncturing the animal's testis and detecting the presence of cAMP responsive element modulator (CREM) and/or CREM-dependent proteins, wherein if CREM is not expressed or expressed only to a reduced extent and not expressed in phosphorylated form, respectively, so that CREM-dependent proteins are not expressed either or expressed only to a reduced extent, there will be unbalanced spermatogenesis resulting in non-functioning spermia, thereby investigating and monitoring spermatogenesis, by using of one or more of (a) to (c):

(a) [primers for] amplifying DNA coding for CREM and/or CREM-dependent proteins present in samples taken from said male animal's testis using primers specific for CREM and/or CREM-dependent proteins together with the necessary standards and detection reagents;

(b) conducting a western blow analysis using antibodies against CREM and/or CREM-dependent proteins to detect the presence of CREM and/or CREM-dependent proteins in samples taken from said male animal's testis together with the necessary standards and detection reagents; or

(c) conducting a northern blot analysis using DNA encoding for CREM or CREM-dependent proteins to detect the presence of CREM or CREM-dependent mRNAs

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Marked-up Claim 5

in samples taken from said male animal's testis together with the necessary standards and detection reagents[;

as well as:

(d) standards and detection reagents for one or more of (a) to (c)].